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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,854	12/09/2003	Kenneth M. Boy	CT-2709 NP	4249

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EXAMINER

MORRIS, PATRICIA L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/731,854

Applicant(s)

BOY ET AL.

Examiner

Patricia L. Morris

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,9 and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2,5-8,10 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

Claims 1, 2, 5-8, 10 and 11 are under consideration in this application.

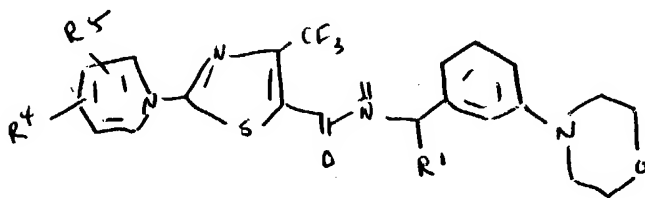
Claims 3, 4, 9 and 12-17 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

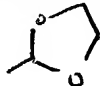
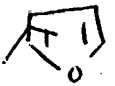

***Election/Restrictions***

Applicant's election with traverse of Group I and example 62 in the reply filed on August 18, 2004 is acknowledged. The traversal is on the ground(s) that the compounds of Groups I and II share significant structural similarity. This is not found persuasive because for the reasons clearly set forth in the previous Office action. Further, applicants have failed to advance any cogent reasons as to why the inventions are not patentably distinct.

The requirement is still deemed sound and proper and is therefore maintained.

This application has been examined with regard to the elected compound and expanded to include a genus wherein



$R^2$  is  $-NR^6R^7$  wherein  $R^6$  and  $R^7$  taken with the nitrogen form a morpholine ring,  $R^4$  is halogen,  $C_{1-6}$ alkyl,  $C_{1-6}$ alkoxy,  $-NR^6R^7$ ,  $-(CH_2)_{1-4}NR^6R^7$ ,  $O(CH_2)_{2-3}NR^6R^7$  or ,  $R^6$  is hydrogen,  $C_{1-6}$ alkyl,  $-C(=NH)NH_2$ ,  or ,  $R^7$  is hydrogen or  $C_{1-6}$ alkyl and  $R^5$  as set forth in Claim 1, exclusively.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The expression solvate is employed in claim 1 with no indication given as to what the solvates really are. It is well known that that solvents can affect chemical stability of the compounds.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The unknown solvates are so broad that they cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

Further there is not indication as to whether the pharmaceutical carriers are able to maintain the solvates claimed. Desolvation may occur. Processing a compound into a pharmaceutical composition could desolvate and even go back to the compound itself.

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There is also no description as to how applicants produced and isolated the particular solvates being claimed. Only when solvent is incorporated into the crystal lattice of the compound in stoichiometric proportions, are particular solvates formed. Applicants would have to show how the particular solvates in the claims are isolated.

The specification has also not described how the solvate forms and their corresponding compositions being claimed will be maintained and prevented from converting to other forms when used in the treatment of inflammation, pain or fever.

The specification lacks direction or guidance for placing all of the alleged products in the possession of the public without inviting more than routine experimentation. Applicants are referred to In re Fouche, 169 USPQ 429 CCPA 1971, MPEP 716.02(b).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

***The nature of the invention***

The nature of the invention is the preparation of novel compounds and solvate forms of the instant compounds and compositions.

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***State of the Prior Art***

Although identical in chemical composition, solvates can have very different properties. Solvates tend to convert from less stable to more stable forms. No method exists to predict the solvates of a solid compound with any significant certainty.

***The amount of direction or guidance and the presence or absence of working examples***

The specification fails to disclose the X-ray diffraction pattern and infrared spectra of compounds of particular solvates and the compositions containing a particular solvates.

***The breadth of the claims***

The breadth of the claims are drawn to the unknown solvates forms in addition to the pharmaceutical compositions.

***The quantity of experimentation needed***

The quantity of experimentation needed would be undue when faced with the lack of direction and guidance present in the instant specification in regards to the solvates and their pharmaceutical compositions being claimed.

In terms of the 8 Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of unpredictability in the art of the invention, and the poor amount of direction provided by applicants. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

***Allowable Subject Matter***

Claims 2, 5-8, 10 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the

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base claim and any intervening claims and if rewritten directed solely to the subject matter indicated as being examined, supra.

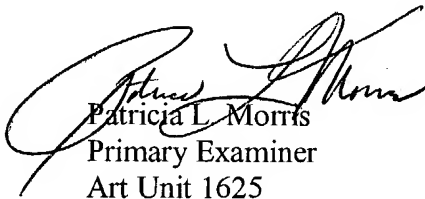
Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112 set forth in this Office action and if rewritten directed solely to the elected compounds.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Morris whose telephone number is (571) 272-0688. The examiner can normally be reached on Mondays through Fridays.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Patricia L. Morris  
Primary Examiner  
Art Unit 1625

plm  
October 12, 2004